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**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEVADA**

AMARIN PHARMA, INC. and AMARIN  
PHARMACEUTICALS IRELAND  
LIMITED,

Plaintiffs,

v.

ROXANE LABORATORIES, INC. and  
HIKMA PHARMACEUTICALS PLC,

Defendants.

Case No.: 2:16-cv-02525

**COMPLAINT FOR PATENT  
INFRINGEMENT**

Plaintiffs Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited (collectively,  
“Plaintiffs” or “Amarin”), by their attorneys, for their complaint against Roxane Laboratories,

1 Inc. (“Roxane”) and Hikma Pharmaceuticals PLC (“Hikma”) (collectively, “Defendants”) allege  
2 as follows:

3 **Nature of the Action**

4 1. This is a civil action for patent infringement arising under the patent laws of the  
5 United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(a-c, e) for  
6 infringement of U.S. Patent No. 8,293,728 (“the ‘728 Patent”), U.S. Patent No. 8,318,715 (“the  
7 ‘715 Patent”), U.S. Patent No. 8,357,677 (“the ‘677 Patent”), U.S. Patent No. 8,367,652 (“the  
8 ‘652 Patent”), U.S. Patent No. 8,377,920 (“the ‘920 Patent”), U.S. Patent No. 8,399,446 (“the  
9 ‘446 Patent”), U.S. Patent No. 8,415,335 (“the ‘335 Patent”), U.S. Patent No. 8,426,399 (“the  
10 ‘399 Patent”), U.S. Patent No. 8,431,560 (“the ‘560 Patent”), U.S. Patent No. 8,440,650 (“the  
11 ‘650 Patent”), U.S. Patent No. 8,518,929 (“the ‘929 Patent”), U.S. Patent No. 8,524,698 (“the  
12 ‘698 Patent”), U.S. Patent No. 8,546,372 (“the ‘372 Patent”), and U.S. Patent No. 8,617,594  
13 (“the ‘594 Patent”). This action relates to an Abbreviated New Drug Application (“ANDA”) No.  
14 209457 filed by or for the benefit of Defendants with the United States Food and Drug  
15 Administration (“FDA”) for approval to market generic versions of Plaintiffs’ VASCEPA®  
16 pharmaceutical products that are sold in the United States, including within this judicial district.  
17 This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331  
18 and 1338(a).

19 **The Parties**

20 2. Plaintiff Amarin Pharma, Inc. is a company organized and existing under the laws  
21 of Delaware with its principal place of business at 1430 Route 206, Bedminster, NJ 07921.

22 3. Plaintiff Amarin Pharmaceuticals Ireland Limited is a company incorporated  
23 under the laws of Ireland with registered offices at 88 Harcourt Street, Dublin 2, Dublin, Ireland.

24 4. Upon information and belief, Defendant Roxane Laboratories, Inc. (“Roxane”) is  
25 a company organized and existing under the laws of Nevada with its principal place of business  
26 at 1809 Wilson Road, Columbus, Ohio.

27 5. Upon information and belief, Defendant Hikma Pharmaceuticals PLC (“Hikma”)  
28

1 is a company organized and existing under the laws of the United Kingdom with its principal  
2 place of business at 13 Hanover Square, London W1S 1HL, United Kingdom.

3 6. Upon information and belief, Roxane is a wholly owned subsidiary of Hikma.

4 7. Upon information and belief, Defendants either directly or through one or more  
5 of their wholly owned subsidiaries and/or agents, develop, manufacture, distribute, market, offer  
6 to sell, and sell generic drug products for sale and use throughout the United States, including  
7 within this judicial district.

8 **Jurisdiction and Venue**

9 8. This is a civil action for patent infringement arising under the patent laws of the  
10 United States, Title 35 of the U.S. Code, for infringement of the '728 Patent, the '715 Patent, the  
11 '677 Patent, the '652 Patent, the '920 Patent, the '446 Patent, the '335 Patent, the '399 Patent,  
12 the '560 Patent, the '650 Patent, the '929 Patent, the '698 Patent, the '372 Patent, and the '594  
13 Patent.

14 9. This Court has jurisdiction over the subject matter of this action pursuant to 28  
15 U.S.C. §§ 1331 and 1338(a).

16 10. Upon information and belief, Roxane is incorporated in Nevada.

17 11. On information and belief and as stated in the ANDA Notice Letter, Defendants  
18 prepared and filed ANDA No. 209457, through Roxane, with the intention of seeking to market  
19 a generic version of Amarin's VASCEPA® product, including within this judicial district.

20 12. Upon information and belief, Defendants regularly conduct business in Nevada,  
21 either directly or through one or more of their wholly owned subsidiaries and/or agents.

22 13. Upon information and belief, Defendants are licensed to sell generic  
23 pharmaceutical products in Nevada, either directly or through one or more of their wholly  
24 owned subsidiaries and/or agents.

25 14. Upon information and belief, Defendants receive Medicaid reimbursements for  
26 drugs sold in Nevada, either directly or through one or more of their wholly owned subsidiaries  
27 and/or agents.

1           15.     Upon information and belief, Defendants plan to sell a generic VASCEPA®  
2 product in Nevada, list a generic VASCEPA® product on Nevada’s prescription drug formulary,  
3 and seek Medicaid reimbursements for sales of a generic VASCEPA® product in Nevada, either  
4 directly or through one or more of their wholly owned subsidiaries and/or agents.

5           16.     On information and belief, by virtue of, *inter alia*, Roxane’s incorporation in  
6 Nevada, as well as Defendants’ sales-related activities in Nevada, including but not limited to the  
7 substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical  
8 products to residents of Nevada described in paragraphs 11–15, this Court has general personal  
9 jurisdiction over Defendants.

10           17.     On information and belief, by virtue of, *inter alia*, Defendants’ continuous and  
11 systematic contacts with Nevada, including but not limited to the contacts described in  
12 paragraphs 11–15, this Court has specific personal jurisdiction over Defendants. These activities  
13 satisfy due process and confer personal jurisdiction over Defendants consistent with Nevada law.  
14 *See, e.g., Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 762–63 (Fed. Cir. 2016)  
15 (holding that minimum-contacts requirement for specific personal jurisdiction is established  
16 where Defendant’s “ANDA filings and its distribution channels establish that [the Defendant]  
17 plans to market its proposed drugs in [the State where the complaint was filed] and the lawsuit is  
18 about patent constraints on such in-State marketing.”).

19           18.     On the basis of at least the facts alleged in paragraphs 10–17, venue is proper in  
20 this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

21                   **Regulatory Requirements for New and Generic Drugs**

22           19.     A person wishing to market a new drug that has not previously been approved by  
23 the U.S. Food and Drug Administration (“FDA”) (a “pioneering” drug) must file a New Drug  
24 Application (“NDA”) with FDA demonstrating that the drug is safe and effective for its  
25 intended use. 21 U.S.C. § 355(b).

26           20.     A person wishing to market a generic copy of a drug that previously has been  
27 approved by FDA may follow a truncated approval process by filing an Abbreviated New Drug  
28

1 Application (“ANDA”) for a generic version of that drug. In the ANDA, the applicant must  
2 demonstrate, among other things, bioequivalence of the generic copy with the pioneering drug.  
3 21 U.S.C. § 355(j)(2)(A)(iv).

4 21. Unlike an NDA applicant, an ANDA applicant is not required to include safety  
5 and effectiveness data. Instead, the ANDA applicant is permitted to rely on the approval of the  
6 NDA applicant’s drug—in essence, piggybacking on the NDA application and safety and  
7 effectiveness conclusions. 21 U.S.C. § 355(j).

8 22. Nor does an ANDA applicant establish any new conditions of use for the  
9 proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of  
10 use that previously have been approved in connection with an approved NDA. 21 U.S.C. §  
11 355(j)(2)(A)(i).

#### 12 **The Approved Drug Product**

13 23. Amarin Pharmaceuticals Ireland Limited is the current holder of NDA No.  
14 202057, for 1g icosapent ethyl capsules, which was first approved by FDA on July 26, 2012.  
15 Amarin Pharma, Inc. is Amarin Pharmaceuticals Ireland Limited’s agent in the United States for  
16 purposes of communicating with FDA regarding NDA No. 202057. Amarin Pharmaceuticals  
17 Ireland Limited and Amarin Pharma, Inc. market the approved drug product under the  
18 tradename VASCEPA®.

19 24. VASCEPA® is indicated as an adjunct to diet to reduce triglyceride levels in adult  
20 patients with severe hypertriglyceridemia. A true, correct, and complete copy of the Prescribing  
21 Information for VASCEPA® approved in NDA No. 202057 is attached as Exhibit A.

22 25. FDA has listed the ‘728, ‘715, ‘677, ‘652, ‘920, ‘446, ‘335, ‘399, ‘560, ‘650, ‘929,  
23 ‘698, ‘372, and ‘594 Patents in the Orange Book—formally known as Approved Drug Products  
24 With Therapeutic Equivalence Evaluations—in connection with NDA No. 202057.

25 26. Amarin Pharmaceuticals Ireland Limited is the owner of the ‘728, ‘715, ‘677, ‘652,  
26 ‘920, ‘446, ‘335, ‘399, ‘560, ‘650, ‘929, ‘698, ‘372, and ‘594 Patents.

**ANDA No. 209457**

27. Upon information and belief, on or before September 21, 2016, Defendants, through Roxane, submitted to FDA an ANDA (ANDA No. 209457) with paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for 1g icosapent ethyl capsules purportedly bioequivalent to VASCEPA®. The purpose of the ANDA is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of a generic VASCEPA® product.

28. Upon information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 209457 for the generic VASCEPA® product is to reduce triglyceride levels in adult patients with severe hypertriglyceridemia, *i.e.*, the same indication as that set forth in the approved labeling for VASCEPA®.

29. Upon information and belief, Defendants, through Roxane, sent Amarin a letter dated September 21, 2016, which was received by Amarin on September 22, 2016 (the “Notice Letter”). The Notice Letter represented that Defendants, through Roxane, had submitted to FDA an ANDA, No. 209457, with a paragraph IV certification for the ‘728, ‘715, ‘677, ‘652, ‘920, ‘446, ‘335, ‘399, ‘560, ‘650, ‘929, ‘698, ‘372, and ‘594 Patents.

30. Upon information and belief, the purpose of the ANDA and paragraph IV certifications is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of a generic version of VASCEPA® before the expiration of the patents listed in the Orange Book for NDA No. 202057. Hence, Defendants’ purpose in submitting ANDA No. 209457 is to market products described therein before expiration of the ‘728, ‘715, ‘677, ‘652, ‘920, ‘446, ‘335, ‘399, ‘560, ‘650, ‘929, ‘698, ‘372, and ‘594 Patents.

31. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

**Count I: Patent Infringement of the ‘728 Patent**

32. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 31

1 above.

2 33. United States Patent No. 8,293,728, entitled “METHODS OF TREATING  
3 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and  
4 Trademark Office on October 23, 2012. Plaintiff Amarin Pharmaceuticals Ireland Limited is the  
5 owner of the ‘728 Patent. A true and complete copy of the ‘728 Patent is attached hereto as  
6 Exhibit B.

7 34. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA  
8 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a  
9 generic version of VASCEPA® before the expiration of the ‘728 Patent.

10 35. Defendants’ manufacture, use, offer for sale, or sale of such product would  
11 infringe the claims of the ‘728 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

12 36. Upon information and belief, if approved, the generic VASCEPA® product for  
13 which approval is sought in Defendants’ ANDA No. 209457 will be administered to human  
14 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe  
15 hypertriglyceridemia. This administration by, for example, physicians would constitute direct  
16 infringement, either literally or under the doctrine of equivalents, of one or more claims of the  
17 ‘728 Patent. Upon information and belief, this infringement will occur at Defendants’ behest,  
18 with their intent, knowledge, and encouragement as a result of, for example, Defendants’ sales,  
19 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride  
20 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,  
21 Defendants will actively induce, encourage, aid, and abet administration of the generic  
22 VASCEPA® product with knowledge that it is in contravention of Plaintiffs’ rights under the  
23 ‘728 Patent.

24 37. Defendants’ manufacture, use, offer for sale, or sale in the United States, or  
25 importation into the United States, of the generic VASCEPA® product for which approval is  
26 sought in ANDA No. 209457 would actively induce and contribute to infringement of the ‘728  
27 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

1           38.     Upon information and belief, as part of the ANDA filing, Defendants  
2 purportedly provided written certification to FDA that the claims of the ‘728 Patent are invalid  
3 and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic version of  
4 VASCEPA®.

5           39.     Defendants gave written notice of their certification of invalidity and/or non-  
6 infringement of the ‘728 Patent, alleging that claims of the ‘728 Patent are invalid and/or that  
7 certain claims would not be infringed by Defendants’ generic version of VASCEPA®, and  
8 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,  
9 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the ‘728  
10 Patent.

11           40.     Defendants have infringed the ‘728 Patent under 35 U.S.C. § 271(e)(2)(A) by  
12 virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA  
13 approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the  
14 expiration of the ‘728 Patent. Moreover, if Defendants commercially use, offer for sale, or sell  
15 their generic version of VASCEPA®, or induce or contribute to such conduct, they would  
16 further infringe the ‘728 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

17           41.     Plaintiffs will be irreparably harmed if Defendants are not enjoined from  
18 infringing or actively inducing or contributing to infringement of the ‘728 Patent. Plaintiffs do  
19 not have an adequate remedy at law.

20                   **Count II: Patent Infringement of the ‘715 Patent**

21           42.     Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 41  
22 above.

23           43.     United States Patent No. 8,318,715, entitled “METHODS OF TREATING  
24 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and  
25 Trademark Office on November 27, 2012. Plaintiff Amarin Pharmaceuticals Ireland Limited is  
26 the owner of the ‘715 Patent. A true and complete copy of the ‘715 Patent along with the  
27 certificate of correction is attached hereto as Exhibit C.  
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1           44.     Upon information and belief, Defendants submitted ANDA No. 209457 to FDA  
2 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a  
3 generic version of VASCEPA® before the expiration of the ‘715 Patent.

4           45.     Defendants’ manufacture, use, offer for sale, or sale of such product would  
5 infringe the claims of the ‘715 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

6           46.     Upon information and belief, if approved, the generic VASCEPA® product for  
7 which approval is sought in Defendants’ ANDA No. 209457 will be administered to human  
8 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe  
9 hypertriglyceridemia. This administration by, for example, physicians would constitute direct  
10 infringement, either literally or under the doctrine of equivalents, of one or more claims of the  
11 ‘715 Patent. Upon information and belief, this infringement will occur at Defendants’ behest,  
12 with their intent, knowledge, and encouragement as a result of, for example, Defendants’ sales,  
13 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride  
14 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,  
15 Defendants will actively induce, encourage, aid, and abet administration of the generic  
16 VASCEPA® product with knowledge that it is in contravention of Plaintiffs’ rights under the  
17 ‘715 Patent.

18           47.     Defendants’ manufacture, use, offer for sale, or sale in the United States, or  
19 importation into the United States, of the generic VASCEPA® product for which approval is  
20 sought in ANDA No. 209457 would actively induce and contribute to infringement of the ‘715  
21 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

22           48.     Upon information and belief, as part of the ANDA filing, Defendants  
23 purportedly provided written certification to FDA that the claims of the ‘715 Patent are invalid  
24 and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic version of  
25 VASCEPA®.

26           49.     Defendants gave written notice of their certification of invalidity and/or non-  
27 infringement of the ‘715 Patent, alleging that claims of the ‘715 Patent are invalid and/or that  
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1 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and  
2 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,  
3 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '715  
4 Patent.

5 50. Defendants have infringed the '715 Patent under 35 U.S.C. § 271(e)(2)(A) by  
6 virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA  
7 approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the  
8 expiration of the '715 Patent. Moreover, if Defendants commercially use, offer for sale, or sell  
9 their generic version of VASCEPA®, or induce or contribute to such conduct, they would  
10 further infringe the '715 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

11 51. Plaintiffs will be irreparably harmed if Defendants are not enjoined from  
12 infringing or actively inducing or contributing to infringement of the '715 Patent. Plaintiffs do  
13 not have an adequate remedy at law.

14 **Count III: Patent Infringement of the '677 Patent**

15 52. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 51  
16 above.

17 53. United States Patent No. 8,357,677, entitled "METHODS OF TREATING  
18 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and  
19 Trademark Office on January 22, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the  
20 owner of the '677 Patent. A true and complete copy of the '677 Patent is attached hereto as  
21 Exhibit D.

22 54. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA  
23 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a  
24 generic version of VASCEPA® before the expiration of the '677 Patent.

25 55. Defendants' manufacture, use, offer for sale, or sale of such product would  
26 infringe the claims of the '677 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

27 56. Upon information and belief, if approved, the generic VASCEPA® product for  
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1 which approval is sought in Defendants' ANDA No. 209457 will be administered to human  
2 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe  
3 hypertriglyceridemia. This administration by, for example, physicians would constitute direct  
4 infringement, either literally or under the doctrine of equivalents, of one or more claims of the  
5 '677 Patent. Upon information and belief, this infringement will occur at Defendants' behest,  
6 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,  
7 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride  
8 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,  
9 Defendants will actively induce, encourage, aid, and abet administration of the generic  
10 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the  
11 '677 Patent.

12 57. Defendants' manufacture, use, offer for sale, or sale in the United States, or  
13 importation into the United States, of the generic VASCEPA® product for which approval is  
14 sought in ANDA No. 209457 would actively induce and contribute to infringement of the '677  
15 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

16 58. Upon information and belief, as part of the ANDA filing, Defendants  
17 purportedly provided written certification to FDA that the claims of the '677 Patent are invalid  
18 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of  
19 VASCEPA®.

20 59. Defendants gave written notice of their certification of invalidity and/or non-  
21 infringement of the '677 Patent, alleging that claims of the '677 Patent are invalid and/or that  
22 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and  
23 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,  
24 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '677  
25 Patent.

26 60. Defendants have infringed the '677 Patent under 35 U.S.C. § 271(e)(2)(A) by  
27 virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA  
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1 approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the  
2 expiration of the ‘677 Patent. Moreover, if Defendants commercially use, offer for sale, or sell  
3 their generic version of VASCEPA®, or induce or contribute to such conduct, they would  
4 further infringe the ‘677 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

5 61. Plaintiffs will be irreparably harmed if Defendants are not enjoined from  
6 infringing or actively inducing or contributing to infringement of the ‘677 Patent. Plaintiffs do  
7 not have an adequate remedy at law.

8 **Count IV: Patent Infringement of the ‘652 Patent**

9 62. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 61  
10 above.

11 63. United States Patent No. 8,367,652, entitled “METHODS OF TREATING  
12 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and  
13 Trademark Office on February 5, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the  
14 owner of the ‘652 Patent. A true and complete copy of the ‘652 Patent is attached hereto as  
15 Exhibit E.

16 64. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA  
17 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a  
18 generic version of VASCEPA® before the expiration of the ‘652 Patent.

19 65. Defendants’ manufacture, use, offer for sale, or sale of such product would  
20 infringe the claims of the ‘652 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

21 66. Upon information and belief, if approved, the generic VASCEPA® product for  
22 which approval is sought in Defendants’ ANDA No. 209457 will be administered to human  
23 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe  
24 hypertriglyceridemia. This administration by, for example, physicians would constitute direct  
25 infringement, either literally or under the doctrine of equivalents, of one or more claims of the  
26 ‘652 Patent. Upon information and belief, this infringement will occur at Defendants’ behest,  
27 with their intent, knowledge, and encouragement as a result of, for example, Defendants’ sales,  
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1 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride  
2 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,  
3 Defendants will actively induce, encourage, aid, and abet administration of the generic  
4 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the  
5 '652 Patent.

6 67. Defendants' manufacture, use, offer for sale, or sale in the United States, or  
7 importation into the United States, of the generic VASCEPA® product for which approval is  
8 sought in ANDA No. 209457 would actively induce and contribute to infringement of the '652  
9 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

10 68. Upon information and belief, as part of the ANDA filing, Defendants  
11 purportedly provided written certification to FDA that the claims of the '652 Patent are invalid  
12 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of  
13 VASCEPA®.

14 69. Defendants gave written notice of their certification of invalidity and/or non-  
15 infringement of the '652 Patent, alleging that claims of the '652 Patent are invalid and/or that  
16 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and  
17 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,  
18 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '652  
19 Patent.

20 70. Defendants have infringed the '652 Patent under 35 U.S.C. § 271(e)(2)(A) by  
21 virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA  
22 approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the  
23 expiration of the '652 Patent. Moreover, if Defendants commercially use, offer for sale, or sell  
24 their generic version of VASCEPA®, or induce or contribute to such conduct, they would  
25 further infringe the '652 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

26 71. Plaintiffs will be irreparably harmed if Defendants are not enjoined from  
27 infringing or actively inducing or contributing to infringement of the '652 Patent. Plaintiffs do  
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not have an adequate remedy at law.

**Count V: Patent Infringement of the '920 Patent**

72. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 71 above.

73. United States Patent No. 8,377,920, entitled "METHODS OF TREATING HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and Trademark Office on February 19, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the '920 Patent. A true and complete copy of the '920 Patent is attached hereto as Exhibit F.

74. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the '920 Patent.

75. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '920 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

76. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in Defendants' ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '920 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales, marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of the generic VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the '920 Patent.

77. Defendants' manufacture, use, offer for sale, or sale in the United States, or

1 importation into the United States, of the generic VASCEPA® product for which approval is  
2 sought in ANDA No. 209457 would actively induce and contribute to infringement of the ‘920  
3 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

4 78. Upon information and belief, as part of the ANDA filing, Defendants  
5 purportedly provided written certification to FDA that the claims of the ‘920 Patent are invalid  
6 and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic version of  
7 VASCEPA®.

8 79. Defendants gave written notice of their certification of invalidity and/or non-  
9 infringement of the ‘920 Patent, alleging that claims of the ‘920 Patent are invalid and/or that  
10 certain claims would not be infringed by Defendants’ generic version of VASCEPA®, and  
11 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,  
12 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the ‘920  
13 Patent.

14 80. Defendants have infringed the ‘920 Patent under 35 U.S.C. § 271(e)(2)(A) by  
15 virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA  
16 approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the  
17 expiration of the ‘920 Patent. Moreover, if Defendants commercially use, offer for sale, or sell  
18 their generic version of VASCEPA®, or induce or contribute to such conduct, they would  
19 further infringe the ‘920 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

20 81. Plaintiffs will be irreparably harmed if Defendants are not enjoined from  
21 infringing or actively inducing or contributing to infringement of the ‘920 Patent. Plaintiffs do  
22 not have an adequate remedy at law.

23 **Count VI: Patent Infringement of the ‘446 Patent**

24 82. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 81  
25 above.

26 83. United States Patent No. 8,399,446, entitled “METHODS OF TREATING  
27 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and  
28



1 Trademark Office on March 19, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the  
2 owner of the '446 Patent. A true and complete copy of the '446 Patent is attached hereto as  
3 Exhibit G.

4 84. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA  
5 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a  
6 generic version of VASCEPA® before the expiration of the '446 Patent.

7 85. Defendants' manufacture, use, offer for sale, or sale of such product would  
8 infringe the claims of the '446 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

9 86. Upon information and belief, if approved, the generic VASCEPA® product for  
10 which approval is sought in Defendants' ANDA No. 209457 will be administered to human  
11 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe  
12 hypertriglyceridemia. This administration by, for example, physicians would constitute direct  
13 infringement, either literally or under the doctrine of equivalents, of one or more claims of the  
14 '446 Patent. Upon information and belief, this infringement will occur at Defendants' behest,  
15 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,  
16 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride  
17 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,  
18 Defendants will actively induce, encourage, aid, and abet administration of the generic  
19 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the  
20 '446 Patent.

21 87. Defendants' manufacture, use, offer for sale, or sale in the United States, or  
22 importation into the United States, of the generic VASCEPA® product for which approval is  
23 sought in ANDA No. 209457 would actively induce and contribute to infringement of the '446  
24 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

25 88. Upon information and belief, as part of the ANDA filing, Defendants  
26 purportedly provided written certification to FDA that the claims of the '446 Patent are invalid  
27 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of  
28



1 VASCEPA®.

2 89. Defendants gave written notice of their certification of invalidity and/or non-  
3 infringement of the '446 Patent, alleging that claims of the '446 Patent are invalid and/or that  
4 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and  
5 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,  
6 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '446  
7 Patent.

8 90. Defendants have infringed the '446 Patent under 35 U.S.C. § 271(e)(2)(A) by  
9 virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA  
10 approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the  
11 expiration of the '446 Patent. Moreover, if Defendants commercially use, offer for sale, or sell  
12 their generic version of VASCEPA®, or induce or contribute to such conduct, they would  
13 further infringe the '446 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

14 91. Plaintiffs will be irreparably harmed if Defendants are not enjoined from  
15 infringing or actively inducing or contributing to infringement of the '446 Patent. Plaintiffs do  
16 not have an adequate remedy at law.

17 **Count VII: Patent Infringement of the '335 Patent**

18 92. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 91  
19 above.

20 93. United States Patent No. 8,415,335, entitled "METHODS OF TREATING  
21 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and  
22 Trademark Office on April 9, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the  
23 owner of the '335 Patent. A true and complete copy of the '335 Patent is attached hereto as  
24 Exhibit H.

25 94. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA  
26 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a  
27 generic version of VASCEPA® before the expiration of the '335 Patent.  
28

1           95. Defendants' manufacture, use, offer for sale, or sale of such product would  
2 infringe the claims of the '335 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

3           96. Upon information and belief, if approved, the generic VASCEPA® product for  
4 which approval is sought in Defendants' ANDA No. 209457 will be administered to human  
5 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe  
6 hypertriglyceridemia. This administration by, for example, physicians would constitute direct  
7 infringement, either literally or under the doctrine of equivalents, of one or more claims of the  
8 '335 Patent. Upon information and belief, this infringement will occur at Defendants' behest,  
9 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,  
10 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride  
11 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,  
12 Defendants will actively induce, encourage, aid, and abet administration of the generic  
13 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the  
14 '335 Patent.

15           97. Defendants' manufacture, use, offer for sale, or sale in the United States, or  
16 importation into the United States, of the generic VASCEPA® product for which approval is  
17 sought in ANDA No. 209457 would actively induce and contribute to infringement of the '335  
18 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

19           98. Upon information and belief, as part of the ANDA filing, Defendants  
20 purportedly provided written certification to FDA that the claims of the '335 Patent are invalid  
21 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of  
22 VASCEPA®.

23           99. Defendants gave written notice of their certification of invalidity and/or non-  
24 infringement of the '335 Patent, alleging that claims of the '335 Patent are invalid and/or that  
25 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and  
26 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,  
27 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '335  
28

1 Patent.

2 100. Defendants have infringed the '335 Patent under 35 U.S.C. § 271(e)(2)(A) by  
3 virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA  
4 approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the  
5 expiration of the '335 Patent. Moreover, if Defendants commercially use, offer for sale, or sell  
6 their generic version of VASCEPA®, or induce or contribute to such conduct, they would  
7 further infringe the '335 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

8 101. Plaintiffs will be irreparably harmed if Defendants are not enjoined from  
9 infringing or actively inducing or contributing to infringement of the '335 Patent. Plaintiffs do  
10 not have an adequate remedy at law.

11 **Count VIII: Patent Infringement of the '399 Patent**

12 102. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to  
13 101 above.

14 103. United States Patent No. 8,426,399, entitled "METHODS OF TREATING  
15 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and  
16 Trademark Office on April 23, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the  
17 owner of the '399 Patent. A true and complete copy of the '399 Patent along with the certificate  
18 of correction is attached hereto as Exhibit I.

19 104. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA  
20 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a  
21 generic version of VASCEPA® before the expiration of the '399 Patent.

22 105. Defendants' manufacture, use, offer for sale, or sale of such product would  
23 infringe the claims of the '399 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

24 106. Upon information and belief, if approved, the generic VASCEPA® product for  
25 which approval is sought in Defendants' ANDA No. 209457 will be administered to human  
26 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe  
27 hypertriglyceridemia. This administration by, for example, physicians would constitute direct  
28

1 infringement, either literally or under the doctrine of equivalents, of one or more claims of the  
2 '399 Patent. Upon information and belief, this infringement will occur at Defendants' behest,  
3 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,  
4 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride  
5 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,  
6 Defendants will actively induce, encourage, aid, and abet administration of the generic  
7 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the  
8 '399 Patent.

9 107. Defendants' manufacture, use, offer for sale, or sale in the United States, or  
10 importation into the United States, of the generic VASCEPA® product for which approval is  
11 sought in ANDA No. 209457 would actively induce and contribute to infringement of the '399  
12 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

13 108. Upon information and belief, as part of the ANDA filing, Defendants  
14 purportedly provided written certification to FDA that the claims of the '399 Patent are invalid  
15 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of  
16 VASCEPA®.

17 109. Defendants gave written notice of their certification of invalidity and/or non-  
18 infringement of the '399 Patent, alleging that claims of the '399 Patent are invalid and/or that  
19 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and  
20 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,  
21 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '399  
22 Patent.

23 110. Defendants have infringed the '399 Patent under 35 U.S.C. § 271(e)(2)(A) by  
24 virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA  
25 approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the  
26 expiration of the '399 Patent. Moreover, if Defendants commercially use, offer for sale, or sell  
27 their generic version of VASCEPA®, or induce or contribute to such conduct, they would  
28

1 further infringe the '399 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

2 111. Plaintiffs will be irreparably harmed if Defendants are not enjoined from  
3 infringing or actively inducing or contributing to infringement of the '399 Patent. Plaintiffs do  
4 not have an adequate remedy at law.

5 **Count IX: Patent Infringement of the '560 Patent**

6 112. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to  
7 111 above.

8 113. United States Patent No. 8,431,560, entitled "METHODS OF TREATING  
9 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and  
10 Trademark Office on April 30, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the  
11 owner of the '560 Patent. A true and complete copy of the '560 Patent is attached hereto as  
12 Exhibit J.

13 114. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA  
14 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a  
15 generic version of VASCEPA® before the expiration of the '560 Patent.

16 115. Defendants' manufacture, use, offer for sale, or sale of such product would  
17 infringe the claims of the '560 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

18 116. Upon information and belief, if approved, the generic VASCEPA® product for  
19 which approval is sought in Defendants' ANDA No. 209457 will be administered to human  
20 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe  
21 hypertriglyceridemia. This administration by, for example, physicians would constitute direct  
22 infringement, either literally or under the doctrine of equivalents, of one or more claims of the  
23 '560 Patent. Upon information and belief, this infringement will occur at Defendants' behest,  
24 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,  
25 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride  
26 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,  
27 Defendants will actively induce, encourage, aid, and abet administration of the generic  
28

1 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the  
2 '560 Patent.

3 117. Defendants' manufacture, use, offer for sale, or sale in the United States, or  
4 importation into the United States, of the generic VASCEPA® product for which approval is  
5 sought in ANDA No. 209457 would actively induce and contribute to infringement of the '560  
6 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

7 118. Upon information and belief, as part of the ANDA filing, Defendants  
8 purportedly provided written certification to FDA that the claims of the '560 Patent are invalid  
9 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of  
10 VASCEPA®.

11 119. Defendants gave written notice of their certification of invalidity and/or non-  
12 infringement of the '560 Patent, alleging that claims of the '560 Patent are invalid and/or that  
13 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and  
14 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,  
15 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '560  
16 Patent.

17 120. Defendants have infringed the '560 Patent under 35 U.S.C. § 271(e)(2)(A) by  
18 virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA  
19 approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the  
20 expiration of the '560 Patent. Moreover, if Defendants commercially use, offer for sale, or sell  
21 their generic version of VASCEPA®, or induce or contribute to such conduct, they would  
22 further infringe the '560 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

23 121. Plaintiffs will be irreparably harmed if Defendants are not enjoined from  
24 infringing or actively inducing or contributing to infringement of the '560 Patent. Plaintiffs do  
25 not have an adequate remedy at law.

26 **Count X: Patent Infringement of the '650 Patent**

27 122. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to  
28

121 above.

123. United States Patent No. 8,440,650, entitled “METHODS OF TREATING HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and Trademark Office on May 14, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the owner of the ‘650 Patent. A true and complete copy of the ‘650 Patent is attached hereto as Exhibit K.

124. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of VASCEPA® before the expiration of the ‘650 Patent.

125. Defendants’ manufacture, use, offer for sale, or sale of such product would infringe the claims of the ‘650 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

126. Upon information and belief, if approved, the generic VASCEPA® product for which approval is sought in Defendants’ ANDA No. 209457 will be administered to human patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. This administration by, for example, physicians would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the ‘650 Patent. Upon information and belief, this infringement will occur at Defendants’ behest, with their intent, knowledge, and encouragement as a result of, for example, Defendants’ sales, marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons, Defendants will actively induce, encourage, aid, and abet administration of the generic VASCEPA® product with knowledge that it is in contravention of Plaintiffs’ rights under the ‘650 Patent.

127. Defendants’ manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic VASCEPA® product for which approval is sought in ANDA No. 209457 would actively induce and contribute to infringement of the ‘650 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).



1           128. Upon information and belief, as part of the ANDA filing, Defendants  
2 purportedly provided written certification to FDA that the claims of the ‘650 Patent are invalid  
3 and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic version of  
4 VASCEPA®.

5           129. Defendants gave written notice of their certification of invalidity and/or non-  
6 infringement of the ‘650 Patent, alleging that claims of the ‘650 Patent are invalid and/or that  
7 certain claims would not be infringed by Defendants’ generic version of VASCEPA®, and  
8 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,  
9 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the ‘650  
10 Patent.

11           130. Defendants have infringed the ‘650 Patent under 35 U.S.C. § 271(e)(2)(A) by  
12 virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA  
13 approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the  
14 expiration of the ‘650 Patent. Moreover, if Defendants commercially use, offer for sale, or sell  
15 their generic version of VASCEPA®, or induce or contribute to such conduct, they would  
16 further infringe the ‘650 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

17           131. Plaintiffs will be irreparably harmed if Defendants are not enjoined from  
18 infringing or actively inducing or contributing to infringement of the ‘650 Patent. Plaintiffs do  
19 not have an adequate remedy at law.

20                   **Count XI: Patent Infringement of the ‘929 Patent**

21           132. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to  
22 131 above.

23           133. United States Patent No. 8,518,929, entitled “METHODS OF TREATING  
24 HYPERTRIGLYCERIDEMIA,” was duly and legally issued by the United States Patent and  
25 Trademark Office on August 27, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the  
26 owner of the ‘929 Patent. A true and complete copy of the ‘929 Patent is attached hereto as  
27 Exhibit L.  
28



1           134. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA  
2 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a  
3 generic version of VASCEPA® before the expiration of the ‘929 Patent.

4           135. Defendants’ manufacture, use, offer for sale, or sale of such product would  
5 infringe the claims of the ‘929 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

6           136. Upon information and belief, if approved, the generic VASCEPA® product for  
7 which approval is sought in Defendants’ ANDA No. 209457 will be administered to human  
8 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe  
9 hypertriglyceridemia. This administration by, for example, physicians would constitute direct  
10 infringement, either literally or under the doctrine of equivalents, of one or more claims of the  
11 ‘929 Patent. Upon information and belief, this infringement will occur at Defendants’ behest,  
12 with their intent, knowledge, and encouragement as a result of, for example, Defendants’ sales,  
13 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride  
14 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,  
15 Defendants will actively induce, encourage, aid, and abet administration of the generic  
16 VASCEPA® product with knowledge that it is in contravention of Plaintiffs’ rights under the  
17 ‘929 Patent.

18           137. Defendants’ manufacture, use, offer for sale, or sale in the United States, or  
19 importation into the United States, of the generic VASCEPA® product for which approval is  
20 sought in ANDA No. 209457 would actively induce and contribute to infringement of the ‘929  
21 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

22           138. Upon information and belief, as part of the ANDA filing, Defendants  
23 purportedly provided written certification to FDA that the claims of the ‘929 Patent are invalid  
24 and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic version of  
25 VASCEPA®.

26           139. Defendants gave written notice of their certification of invalidity and/or non-  
27 infringement of the ‘929 Patent, alleging that claims of the ‘929 Patent are invalid and/or that  
28

1 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and  
2 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,  
3 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '929  
4 Patent.

5 140. Defendants have infringed the '929 Patent under 35 U.S.C. § 271(e)(2)(A) by  
6 virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA  
7 approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the  
8 expiration of the '929 Patent. Moreover, if Defendants commercially use, offer for sale, or sell  
9 their generic version of VASCEPA®, or induce or contribute to such conduct, they would  
10 further infringe the '929 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

11 141. Plaintiffs will be irreparably harmed if Defendants are not enjoined from  
12 infringing or actively inducing or contributing to infringement of the '929 Patent. Plaintiffs do  
13 not have an adequate remedy at law.

14 **Count XII: Patent Infringement of the '698 Patent**

15 142. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to  
16 141 above.

17 143. United States Patent No. 8,524,698, entitled "METHODS OF TREATING  
18 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and  
19 Trademark Office on September 3, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is  
20 the owner of the '698 Patent. A true and complete copy of the '698 Patent along with the  
21 certificate of correction is attached hereto as Exhibit M.

22 144. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA  
23 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a  
24 generic version of VASCEPA® before the expiration of the '698 Patent.

25 145. Defendants' manufacture, use, offer for sale, or sale of such product would  
26 infringe the claims of the '698 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

27 146. Upon information and belief, if approved, the generic VASCEPA® product for  
28

1 which approval is sought in Defendants' ANDA No. 209457 will be administered to human  
2 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe  
3 hypertriglyceridemia. This administration by, for example, physicians would constitute direct  
4 infringement, either literally or under the doctrine of equivalents, of one or more claims of the  
5 '698 Patent. Upon information and belief, this infringement will occur at Defendants' behest,  
6 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,  
7 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride  
8 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,  
9 Defendants will actively induce, encourage, aid, and abet administration of the generic  
10 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the  
11 '698 Patent.

12 147. Defendants' manufacture, use, offer for sale, or sale in the United States, or  
13 importation into the United States, of the generic VASCEPA® product for which approval is  
14 sought in ANDA No. 209457 would actively induce and contribute to infringement of the '698  
15 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

16 148. Upon information and belief, as part of the ANDA filing, Defendants  
17 purportedly provided written certification to FDA that the claims of the '698 Patent are invalid  
18 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of  
19 VASCEPA®.

20 149. Defendants gave written notice of their certification of invalidity and/or non-  
21 infringement of the '698 Patent, alleging that claims of the '698 Patent are invalid and/or that  
22 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and  
23 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,  
24 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '698  
25 Patent.

26 150. Defendants have infringed the '698 Patent under 35 U.S.C. § 271(e)(2)(A) by  
27 virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA  
28

1 approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the  
2 expiration of the '698 Patent. Moreover, if Defendants commercially use, offer for sale, or sell  
3 their generic version of VASCEPA®, or induce or contribute to such conduct, they would  
4 further infringe the '698 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

5 151. Plaintiffs will be irreparably harmed if Defendants are not enjoined from  
6 infringing or actively inducing or contributing to infringement of the '698 Patent. Plaintiffs do  
7 not have an adequate remedy at law.

8 **Count XIII: Patent Infringement of the '372 Patent**

9 152. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to  
10 151 above.

11 153. United States Patent No. 8,546,372, entitled "METHODS OF TREATING  
12 HYPERTRIGLYCERIDEMIA," was duly and legally issued by the United States Patent and  
13 Trademark Office on October 1, 2013. Plaintiff Amarin Pharmaceuticals Ireland Limited is the  
14 owner of the '372 Patent. A true and complete copy of the '372 Patent is attached hereto as  
15 Exhibit N.

16 154. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA  
17 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a  
18 generic version of VASCEPA® before the expiration of the '372 Patent.

19 155. Defendants' manufacture, use, offer for sale, or sale of such product would  
20 infringe the claims of the '372 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

21 156. Upon information and belief, if approved, the generic VASCEPA® product for  
22 which approval is sought in Defendants' ANDA No. 209457 will be administered to human  
23 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe  
24 hypertriglyceridemia. This administration by, for example, physicians would constitute direct  
25 infringement, either literally or under the doctrine of equivalents, of one or more claims of the  
26 '372 Patent. Upon information and belief, this infringement will occur at Defendants' behest,  
27 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,  
28

1 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride  
2 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,  
3 Defendants will actively induce, encourage, aid, and abet administration of the generic  
4 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the  
5 '372 Patent.

6 157. Defendants' manufacture, use, offer for sale, or sale in the United States, or  
7 importation into the United States, of the generic VASCEPA® product for which approval is  
8 sought in ANDA No. 209457 would actively induce and contribute to infringement of the '372  
9 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

10 158. Upon information and belief, as part of the ANDA filing, Defendants  
11 purportedly provided written certification to FDA that the claims of the '372 Patent are invalid  
12 and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of  
13 VASCEPA®.

14 159. Defendants gave written notice of their certification of invalidity and/or non-  
15 infringement of the '372 Patent, alleging that claims of the '372 Patent are invalid and/or that  
16 certain claims would not be infringed by Defendants' generic version of VASCEPA®, and  
17 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,  
18 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the '372  
19 Patent.

20 160. Defendants have infringed the '372 Patent under 35 U.S.C. § 271(e)(2)(A) by  
21 virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA  
22 approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the  
23 expiration of the '372 Patent. Moreover, if Defendants commercially use, offer for sale, or sell  
24 their generic version of VASCEPA®, or induce or contribute to such conduct, they would  
25 further infringe the '372 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

26 161. Plaintiffs will be irreparably harmed if Defendants are not enjoined from  
27 infringing or actively inducing or contributing to infringement of the '372 Patent. Plaintiffs do  
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1 not have an adequate remedy at law.

2 **Count XIV: Patent Infringement of the '594 Patent**

3 162. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to  
4 161 above.

5 163. United States Patent No. 8,617,594, entitled "STABLE PHARMACEUTICAL  
6 COMPOSITION AND METHODS OF USING SAME," was duly and legally issued by the  
7 United States Patent and Trademark Office on December 31, 2013. Plaintiff Amarin  
8 Pharmaceuticals Ireland Limited is the owner of the '594 Patent. A true and complete copy of  
9 the '594 Patent is attached hereto as Exhibit O.

10 164. Upon information and belief, Defendants submitted ANDA No. 209457 to FDA  
11 seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a  
12 generic version of VASCEPA® before the expiration of the '594 Patent.

13 165. Defendants' manufacture, use, offer for sale, or sale of such product would  
14 infringe the claims of the '594 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

15 166. Upon information and belief, if approved, the generic VASCEPA® product for  
16 which approval is sought in Defendants' ANDA No. 209457 will be administered to human  
17 patients as an adjunct to diet to reduce triglyceride levels in adult patients with severe  
18 hypertriglyceridemia. This administration by, for example, physicians would constitute direct  
19 infringement, either literally or under the doctrine of equivalents, of one or more claims of the  
20 '594 Patent. Upon information and belief, this infringement will occur at Defendants' behest,  
21 with their intent, knowledge, and encouragement as a result of, for example, Defendants' sales,  
22 marketing, and distribution of their ANDA Product as an adjunct to diet to reduce triglyceride  
23 levels in adult patients with severe hypertriglyceridemia. Therefore, for at least these reasons,  
24 Defendants will actively induce, encourage, aid, and abet administration of the generic  
25 VASCEPA® product with knowledge that it is in contravention of Plaintiffs' rights under the  
26 '594 Patent.

27 167. Defendants' manufacture, use, offer for sale, or sale in the United States, or  
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1 importation into the United States, of the generic VASCEPA® product for which approval is  
2 sought in ANDA No. 209457 would actively induce and contribute to infringement of the ‘594  
3 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

4 168. Upon information and belief, as part of the ANDA filing, Defendants  
5 purportedly provided written certification to FDA that the claims of the ‘594 Patent are invalid  
6 and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic version of  
7 VASCEPA®.

8 169. Defendants gave written notice of their certification of invalidity and/or non-  
9 infringement of the ‘594 Patent, alleging that claims of the ‘594 Patent are invalid and/or that  
10 certain claims would not be infringed by Defendants’ generic version of VASCEPA®, and  
11 informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,  
12 use, and sale of a product bioequivalent to VASCEPA® prior to the expiration of the ‘594  
13 Patent.

14 170. Defendants have infringed the ‘594 Patent under 35 U.S.C. § 271(e)(2)(A) by  
15 virtue of submitting ANDA No. 209457 with a paragraph IV certification and seeking FDA  
16 approval of ANDA No. 209457 to market a generic version of VASCEPA® prior to the  
17 expiration of the ‘594 Patent. Moreover, if Defendants commercially use, offer for sale, or sell  
18 their generic version of VASCEPA®, or induce or contribute to such conduct, they would  
19 further infringe the ‘594 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

20 171. Plaintiffs will be irreparably harmed if Defendants are not enjoined from  
21 infringing or actively inducing or contributing to infringement of the ‘594 Patent. Plaintiffs do  
22 not have an adequate remedy at law.

23 **Prayer for Relief**

24 WHEREFORE, Plaintiffs seek the following relief:

25 A. A judgment that Defendants have infringed the ‘728, ‘715, ‘677, ‘652, ‘920, ‘446,  
26 ‘335, ‘399, ‘560, ‘650, ‘929, ‘698, ‘372, and ‘594 Patents under 35 U.S.C. § 271(e)(2)(A);

27 B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of  
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any FDA approval of ANDA No. 209457 is not earlier than the expiration date of the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents, or any later expiration of exclusivity for the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents to which Plaintiffs are or become entitled;

C. A permanent injunction restraining and enjoining Defendants and their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing any product that infringes the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents, including the product described in ANDA No. 209457;

D. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 209457, or inducing or contributing to such conduct, would constitute infringement of the '728, '715, '677, '652, '920, '446, '335, '399, '560, '650, '929, '698, '372, and '594 Patents by Defendants pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

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1 G. Such further and other relief as this Court determines to be just and proper.

2 DATED: October 31, 2016

Respectfully submitted,

3 /s/ Nicholas J. Santoro

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